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09/100812

APPLICATION NO. 09/100812	FILING DATE 05/19/98	FIRST NAMED INVENTOR GRAHAM	ATTORNEY DOCKET NO. M 11535
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EXAMINER KAUSHAL, S

ART UNIT 1633	PAPER NUMBER 5
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DATE MAILED: 12/02/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/100,812

Applicant(s)
GRAHAM

Examiner
SUMESH KAUSHAL

Group Art Unit
1633



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-33 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-33 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit:

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5, drawn to a synthetic gene and a gene construct capable of modifying target gene expression in a cell, tissue, organ or organism, and a cell, tissue organ or organism comprising the synthetic gene and genetic constructs classified in class 514, subclass 44.
 - II. Claim 6, drawn to plasmid pEGFP-N1 MCS or derivative thereof, classified in class 536, subclass 23.1.
 - III. Claim 7, drawn to plasmid pCMV.cass or derivative thereof, classified in class 536, subclass 23.1.
 - IV. Claim 8, drawn to plasmid pCR.Bgl-GFP or derivative thereof, classified in class 536, subclass 23.1.
 - V. Claim 9, drawn to plasmid pCR.SV40L or derivative thereof, classified in class 536, subclass 23.1.
 - VI. Claim 10, drawn to plasmid pCMV.SV40L or derivative thereof, classified in class 536, subclass 23.1.

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- VII. Claim 11, drawn to plasmid pCR.BEV.1 or derivative thereof, classified in class 536, subclass 23.1.
- VIII. Claim 12, drawn to plasmid pCR.BEV.2 or derivative thereof, classified in class 536, subclass 23.1.
- IX. Claim 13, drawn to plasmid pCR.BEV.3 or derivative thereof, classified in class 536, subclass 23.1.
- X. Claim 14, drawn to plasmid pEGFP-N1 MCS or derivative thereof, classified in class 536, subclass 23.1.
- XI. Claim 15, drawn to plasmid pCMV.BEV.2 or derivative thereof, classified in class 536, subclass 23.1.
- XII. Claim 16, drawn to plasmid pCR.VEB or derivative thereof, classified in class 536, subclass 23.1.
- XIII. Claim 17, drawn to plasmid pCMV.BEVnt or derivative thereof, classified in class 536, subclass 23.1.
- XIV. Claim 18, drawn to plasmid pCMV.BEVx2 or derivative thereof, classified in class 536, subclass 23.1.
- XV. Claim 19, drawn to plasmid pCMV.BEV.VEB or derivative thereof, classified in class 536, subclass 23.1.

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- XVI. Claim 20, drawn to plasmid pCMV.BEV.GFP.VEB or derivative thereof, classified in class 536, subclass 23.1.
- XVII. Claim 21, drawn to plasmid pCMV.BEV.SV40L-0 or derivative thereof, classified in class 536, subclass 23.1.
- XVIII. Claim 22, drawn to plasmid pCMV.0.SV40L.BEV or derivative thereof, classified in class 536, subclass 23.1.
- XIX. Claim 23, drawn to plasmid pCMV.0.SV40L.VEB or derivative thereof, classified in class 536, subclass 23.1.
- XX. Claim 24, drawn to plasmid pCMV.BEV.SV40L.BEV or derivative thereof, classified in class 536, subclass 23.1.
- XXI. Claim 25, drawn to plasmid pCMV.BEV.SV40L.VEB or derivative thereof, classified in class 536, subclass 23.1.
- XXII. Claim 26, drawn to plasmid pCMV.SV40LR.cass or derivative thereof, classified in class 536, subclass 23.1.
- XXIII. Claim 27, drawn to plasmid pCMV.BEV.SV40LR or derivative thereof, classified in class 536, subclass 23.1.

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- XXIV. Claim 28, drawn to plasmid pCMV.TYR or derivative thereof, classified in class 536, subclass 23.1.
- XXV. Claim 29, drawn to plasmid pCMV.TYRLIB or derivative thereof, classified in class 536, subclass 23.1.
- XXVI. Claim 30, drawn to plasmid pCMV.lac or derivative thereof, classified in class 536, subclass 23.1.
- XXVII. Claim 31, drawn to plasmid pCMVLacI.OPRSV1.cass or derivative thereof, classified in class 536, subclass 23.1.
- XXVIII. Claim 32, drawn to plasmid pCMVLacI.OPRSV1.GFP or derivative thereof, classified in class 536, subclass 23.1.
- XXIX. Claim 33, drawn to plasmid pCMVLacI.TYR.OPRSV1.GFP or derivative thereof, classified in class 536, subclass 23.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-XXIX are distinct from each other. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the synthetic gene can also be delivered to cell via viral vectors, whereas plasmids can also be used as cloning vectors to make novel gene constructs. Furthermore, different plasmids have different

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structure, function and are capable of exhibiting different effects. Thus, inventions are distinct and are capable of separate use.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

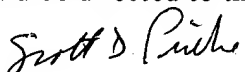
4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jasmine Chambers Ph.D. can be reached on (703) 308-2035. The fax phone number for the organization where this application or proceeding is assigned as (703) 308-2035. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-0196.

Sumesh Kaushal
Art Group 1633


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER